Article - Health - General

[Previous][Next]

§21–2C–09.

(a) (1) After identifying prescription drug products as required by § 21–2C–08 of this subtitle, the Board shall determine whether to conduct a cost review as described in subsection (b) of this section for each identified prescription drug product by:

(i) Seeking Stakeholder Council input about the prescription drug product; and

(ii) Considering the average cost share of the prescription drug product.

(2) (i) To the extent there is no publicly available information to conduct a cost review as described in subsection (b) of this section, the Board shall request the information from:

1. The manufacturer of the prescription drug product; and

2. As appropriate, a wholesale distributor, pharmacy benefits manager, health insurance carrier, health maintenance organization, or managed care organization with relevant information on setting the cost of the prescription drug product in the State.

(ii) The information to conduct a cost review may include any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in the State, market competition and context, projected revenue, and the estimated value or cost–effectiveness of the prescription drug product.

(iii) Failure of a manufacturer, wholesale distributor, pharmacy benefits manager, health insurance carrier, health maintenance organization, or managed care organization to provide the Board with the information requested under this paragraph does not affect the authority of the Board to conduct a review as described in subsection (b) of this section.

(b) (1) If the Board conducts a review of the cost of a prescription drug product, the review shall determine whether use of the prescription drug product that

is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients.

(2) To the extent practicable, in determining whether a prescription drug product identified under § 21–2C–08 of this subtitle has led or will lead to an affordability challenge, the Board shall consider the following factors:

(i) The wholesale acquisition cost and any other relevant prescription drug cost index for the prescription drug product sold in the State;

(ii) The average monetary price concession, discount, or rebate the manufacturer provides to health plans in the State or is expected to provide to health plans in the State as reported by manufacturers and health plans, expressed as a percent of the wholesale acquisition cost for the prescription drug product under review;

(iii) The total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefits manager operating in the State for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a percent of the wholesale acquisition costs;

(iv) The price at which therapeutic alternatives have been sold in the State;

(v) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefits managers in the State for therapeutic alternatives;

(vi) The costs to health plans based on patient access consistent with United States Food and Drug Administration labeled indications;

(vii) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

(viii) The current or expected dollar value of drug–specific patient access programs that are supported by the manufacturer;

(ix) The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

(x) The average patient copay or other cost–sharing for the prescription drug product in the State; and

(xi) Any other factors as determined by the Board in regulations adopted by the Board.

(3) If the Board is unable to determine whether a prescription drug product will produce or has produced challenges to the affordability of the drug for the State health care system, using the factors listed in paragraph (2) of this subsection, the Board may consider the following factors:

(i) The manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the Federal Securities and Exchange Commission for the most recent tax year in proportion to the manufacturer's sales in the State;

(ii) The portion of direct–to–consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer in–State sales to total manufacturer sales in the United States for the product under review;

(iii) Gross and net manufacturer, pharmacy benefits manager, and wholesale distributor revenues for the prescription drug product under review for the most recent tax year;

(iv) Any additional factors proposed by the manufacturer and appropriate health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers that the Board considers relevant; and

(v) Any additional factors as established by the Board in regulations.

(c) On or before December 31, 2020, and each December 31 thereafter, the Board shall submit to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, a report that includes:

(1) Price trends for prescription drug products;

(2) The number of prescription drug products that were subject to Board review and the results of the review; and

(3) Any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

[Previous][Next]